



IN THE
Supreme Court of the United States

October Term 1984

11
No. 83-1925

HILLSBOROUGH COUNTY, FLORIDA, et al.,
Appellants

v.

AUTOMATED MEDICAL LABORATORIES, INC.,
Appellees

On appeal from the
UNITED STATES COURT OF APPEALS
for the Eleventh Circuit

BRIEF AMICUS CURIAE OF THE AMERICAN
BLOOD COMMISSION IN SUPPORT OF THE
DECISION OF THE COURT OF APPEALS.

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The American Blood Commission has
received written consent of the Appellant and
the Appellee for the filing of this amicus
brief.

INTEREST OF AMICUS

The American Blood Commission is a non-governmental organization established to help assure all the people of the nation of a safe and adequate supply of blood and blood components.

The Commission was created in 1975 at the invitation of the Secretary of Health, Education and Welfare, issued to organizations in the private sector concerned with blood services and the uses of blood and its derivatives. The mission of the American Blood Commission was to implement the National Blood Policy promulgated by the secretary in the private sector.

The members of the Commission include organizations that collect and distribute over ninety percent of the blood and blood components used in transfusions and some of the plasma required for the nation's health care; they also include organizations representing blood donors and users of blood products. A list of the members appears in the body of this brief.

(2)

The members of the Court are fully aware that human blood, its components and its derivatives are now an essential element in health care. In addition, no artificial substitute for it exists. Consequently any threat to the system of distribution of blood products throughout the nation is of major national importance and a direct concern not only to the members of the American Blood Commission, but also to the donors and the recipients of blood and blood products.

Ordinances and regulations of the type promulgated by Hillsborough County in Florida and involved in this case could seriously interfere with the availability of blood and its components collected and distributed under the current system of sharing blood resources developed by the private sector organizations. That system involves, under mandate of Congress, the strict regulation and licensing of blood services facilities by United States Government agencies, whether

(3)

the facilities are not-for-profit or commercial, and whether they produce red cells and derivatives, or only plasma and its derivatives.

By virtue of the uniform federal system of control over donations, processing and storing, demands from all parts of the country are being filled without fear of contamination through improper procedures required by local governmental units. The Hillsborough County ordinances and regulations are just such potentially damaging measures. Consequently the American Blood Commission files a brief *amicus curiae* to explain how measures of that kind (a) can do harm to the blood service system of the nation; (b) can impose a serious burden on the movement of a vital product in interstate commerce; and (c) consequently, under the Supremacy Clause of Article VI of the Constitution, are impermissible invasions of an area of regulation preempted by Congress.

STATEMENT

The appellee in this case operates commercial centers for the production of plasma by plasmapheresis. Plasma is the fluid portion of blood that carries all the components of blood to every part of the body. When whole blood is extracted in a donor center, it contains red blood cells and plasma, which together include all the elements that compose the unique substance called "blood." The red blood cells are readily separated from plasma after blood has been drawn from a donor's veins. In the pheresis process, the red blood cells are returned to the donor, and the plasma is further processed into products for transfusion and other health uses.

All aspects of the collection of blood and its derivatives are subject to control by comprehensive federal statutes and regulations to assure safety of donors at the start of the process and to patients receiving these transfusions

to improve their health status. 42 U.S. Code, Sec. 262. In 1980, Hillsborough County adopted several ordinances adding requirements in the plasmapheresis process when operated by commercial organizations. Most, but not all, of the plasma collected and processed in the United States is produced by commercial organizations similar to those operated by appellee.

The appellee brought an action in U.S. District Court for the Middle District of Florida for a declaration of invalidity of the Hillsborough ordinances on the ground of incompatibility with the preempting federal regulatory system, and therefore invalid under the Supremacy Clause of Article VI of the Constitution. The District Court found one part of the ordinances inconsistent with the Constitution but upheld the balance. The Court of Appeals affirmed as to the holding of invalidity, but reversed as to the balance of the ordinances, stating that all the

ordinances were preempted by the federal scheme of regulation, which would be "adversely affected" by the County measures. (722 F. 2d 1526 (1984.))

The County appealed, and this Court noted probable jurisdiction on January 14, 1985.

SUMMARY OF ARGUMENT

The successful operation of a pluralistic national system of collection and distribution of a safe and adequate supply of blood and blood products depends on a continuous flow of donations by individuals motivated by a public interest in supporting the health care of fellow citizens. Anything that jeopardizes the effective operation of that system jeopardizes the life and welfare of every patient needing transfusion of blood or a blood product. The United States Congress has, by statute supported by regulation, provided for comprehensive licensing, inspection and testing of blood

services. The scope of the federal government regime of regulation evidences its intention to occupy the field. Any state or local statute or regulation that adds to or subtracts from that regime, or otherwise threatens to obstruct or interfere with it, is preempted and is invalid under the Supremacy Clause of Article VI of the Constitution. The Hillsborough County ordinances threaten that obstruction and interference and therefore were properly held invalid by the Court of Appeals.

ARGUMENT

The American Blood Commission presents this brief as *amicus curiae* because of its conviction that the uncoordinated intervention of state and other governmental units, besides the federal government, in the regulation of the blood service system could seriously interfere with and do damage to the nationwide availability and distribution of a unique

product that is essential in our health care system. The Commission supports the holding of the Court of Appeals that the Constitution protects the people of the nation from the harm that could result from local action in an area that is national in scope and that has been subject to comprehensive regulation by authority of Congress.

THE AMERICAN BLOOD COMMISSION AND THE NATIONAL BLOOD POLICY

The American Blood Commission is a non-governmental organization established to help assure all the people of the nation of a safe and adequate supply of blood and blood components. The Commission was created in 1975 at the invitation of the Secretary of Health, Education and Welfare, issued to organizations in the private sector concerned with blood services and the uses of blood, its components and derivatives. In 1973 the Secretary of Health, Education and Welfare announced a "National

Blood Policy," calling for "a pluralistic and evolutionary approach to the solution of blood collection and distribution problems." (Federal Register, Vol. 39, September 10, 1974, page 32703.)

In 1974, the Secretary approved a plan for the establishment of an American Blood Commission and announced the Department's intention to cooperate with the Commission in implementing the National Blood Policy. (39 F.R. 32707, Sept. 10, 1974). The Commission was formally established in 1975 and has carried out this mandate for ten years. A historical summary of the American Blood Commission was published in the October, 1978 issue of Lab World, page 22. The present membership of the Commission consists of the following national, not-for-profit organizations:

American Association for Histocompatibility and Immunogenetics
American Association of Blood Banks
American Association of Donor Recruitment Professionals
American Association of Retired Persons
American Association of Tissue Banks

American College of Physicians
 American College of Surgeons
 American Federation of Labor-Congress of
 Industrial Organizations
 American Heart Association
 American Hospital Association
 American Legion
 American Medical Association
 American Nurses' Association
 American Osteopathic Association
 American Red Cross
 American Society for Apheresis
 American Society of Anesthesiologists
 American Society of Clinical Pathologists
 American Society of Hematology
 Blue Cross/Blue Shield Association
 College of American Pathologists
 Communications Workers of America
 Cooley's Anemia Foundation
 Council of Community Blood Centers
 Health Insurance Association of America
 Leukemia Society of America
 National Association for Sickle Cell
 Disease, Inc.
 National Association of Patients on
 Hemodialysis and Transplantation, Inc.
 National Kidney Foundation
 Pharmaceutical Manufacturers Association
 The National Hemophilia Foundation
 United Way of America
 Veterans Administration

THE NATURE OF BLOOD SERVICES

Blood is a unique substance, and the blood services industry is a unique feature of human society. Because science has not developed an artificial substitute for blood, only one source exists: the human veins and arteries through which flows this essential

"river of life." To fill the needs of operating rooms throughout the nation and in every home of a hemophiliac patient, a parade of individual donors must continuously donate their units of blood in every part of the country. An accident or other emergency on the west coast may create an immediate need for types of blood available only on the east coast. The doctors, the hospitals and the patients must have full confidence that the blood bags sent by jet transport contain safe, healthful blood of the required type. The need is national in scope; the assurance must have a national imprimatur.

The system of collection and delivery of blood and its components calls for a special alliance between the individuals who voluntarily offer their veins for the drawing of blood and the institutions that provide the services of the system. Some of those institutions collect, prepare and distribute the blood and its products; others prescribe

the measures that provide its purity and safety; and finally the hospitals and doctors deal with the direct needs of patients. Thus is formed the chain that now provides this essential element in the nation's health care. The National Blood Policy reflects official recognition of the importance of this alliance among individual donors, private organizations and government agencies.

Anything that threatens the alliance and its mechanism is a threat to health care everywhere in the nation.

THE THREAT FROM LOCAL REGULATION

The federal government has promulgated, by statute and regulation, comprehensive rules concerning the blood service system of the nation. The scope of those rules is demonstrated by the embracing language of the authorizing statutory provisions, found in the Appendix of this brief.

These enactments of the federal government,

by their very words, evidence the Congressional intent to "occupy the field" of assuring the safety of the nation's blood services. No express statement of that intention is needed: "Even if Congress has not expressly preemptions state law in a given area, a state statute may nevertheless be invalid under the Supremacy Clause if it conflicts with federal law or 'stands as an obstacle to the accomplishment of the full purposes and objectives of Congress'." Lawrence County v. Lead-Deadwood School District, decided January 9, 1985, 105 S.Ct. 695, 698, quoting from Silkwood v. Kerr-McGee Corporation, decided January 11, 1984, 104 S.Ct. 615. In many ways, regulation of blood services by governmental units and agencies other than the federal government can create conflicts and obstacles in the effective operation of the blood service system envisioned in the National Blood Policy. The Court of Appeals in the present case found that the Hillsborough County ordinances impose "burdensome and

expensive requirements" beyond the "comprehensive federal scheme" in one essential element in that system, and that it would consequently be "adversely affected." If the analysis by the Court of Appeals is correct, the ordinances could not survive the command of the Supremacy Clause.

THE COUNTY ORDINANCES

The Hillsborough County ordinances involved in this case are addressed only to the collection of plasma from donors.

Plasma is "the fluid that is contained within the cardiovascular system"; it provides the carrier or "medium of exchange" of the numerous minerals and other substances that circulate through the body. Plasma is readily separated from the red cells and each part is processed separately. A large proportion of the plasma and plasma derivatives is collected, processed and distributed through commercial blood banks and pharmaceutical concerns.

Most of the red cells and their components, on the other hand, are collected, processed and distributed for transfusions in a not-for-profit context, starting with donors who receive no pay for their donations and passing through a non-commercial system to their ultimate destination in the operating rooms.

The members of the American Blood Commission are all not-for-profit organizations. Only a relatively small part of the products that pass through their hands is plasma. Nonetheless, the outcome of this case is of great concern to them. If local governmental units, by their effort to regulate health services, can interfere with the collection and distribution of one blood product, such as plasma, by commercial organizations, they can also impede the delivery of a safe and adequate blood supply donated voluntarily for patient use. This is why the Commission has entered the present case.

The Hillsborough County ordinances will

potentially cause harm to the blood service system in several ways. They are adequately described in the opinion of the Court of Appeals and in the briefs filed on behalf of the Medical Laboratory and the American Blood Resources Association. A description of one threatening provision should suffice in this amicus brief.

Ordinance 80-12 first cites the federal regulations applicable to plasma. Then the Ordinance adds several requirements for donors of plasma through the "plasmapheresis" process. The Ordinance requires the following procedures over and above the requirements of the federal regulations:

1. Every donor must obtain from County authorities a "donor registration card" that will be valid for six months;
2. The donor registration card will be issued only after a complete physical examination and a hepatitis test;
3. Reports on a daily basis to the

County Health Department;

4. Breathanalysis of each donor immediately prior to donation; and
5. Payment to the County of \$1.00 for each application of phasmapheresis.

These requirements create conflict with the federal system by requiring a donor ID card every six months, by requiring a complete physical examination of the donor before donating, instead of testing the drawn blood for Hepatitis B - "surface antigen" as required by the federal regulations, and by exacting a fee of \$1.00 for each donation. All of these requirements obviously could create complications incident to the collection of plasma.

If local ordinances, statutes or regulations begin to appear in many parts of the country, the situation could become extremely damaging. Already, for example, the California legislature is considering a bill imposing restrictions on blood donating and banking that on its face would conflict with the system of regulations

f the federal government. Assembly Bill No. 88, California Legislature 1985-86, Regular session.

Anything that causes public hesitancy to contribute blood and blood products of any kind is dangerous, and today it has become doubly harmful. The widely publicized development of a new disease, AIDS (Acquired Immune Deficiency Syndrome) and its suspected connection with blood and derivatives, has contributed to public fears about blood donations. Although experts consider those fears are unwarranted, they threaten the delicate tie of individual donors to the system of voluntary donations that underlies the National Blood Policy. Consequently, the national interest requires the avoidance of any obstacle to blood donations that is not needed for the protection of public health. Since the federal government has determined the full measure of what is needed for that purpose, the interference of the County Ordinances cannot be allowed to invade the domain

preempted by acts of Congress.

THE LAW OF PREEMPTION

Long history supports the principle that the Supremacy Clause of Article VI of the Constitution disables states and local units from intruding with inconsistent actions where the federal government has acted. The principle has been summarized and supported with precedents of this Court in terse sentences in Professor Laurence Tribe's "American Constitutional Law":

" . . . state action may . . . be struck down if it is in 'actual conflict' with the objectives that underlie federal enactments (page 378.) . . . the Court will now sanction state regulations that supplement federal efforts so long as compliance with the letter or effectuation of the purpose of the federal enactment is not likely to be impeded by the state law. (page 379) . . . where a multiplicity of federal regulations govern a given field, the pervasiveness of the regulations will help to sustain a conclusion that Congress intended to

exercise exclusive control over the subject matter. (page 385)" 1

An indication of the Congressional intention to preempt the field of blood services appears in the section of the Code following the section which deals with blood. That following section (§263) deals with laboratory examination of human materials. In subsections (k) and (l), it states that certain regulations of the states "not inconsistent with the provisions of this section" are not affected by the federal regulations, or may be exempted by the Secretary. No such provisions were attached to the provisions regulating blood donations, processing and distribution on a national basis. Congress intended to keep those functions exclusively in federal hands.

1. The authorities cited by Professor Tribe for these statements are: Page 378: Nash v. Florida Industrial Commission, 389 U.S. 235, 239 (1967); page 379: Amalgamated Association of Street Electric Railway & Motor Coach Employees of America v. Lockridge, 403 U.S. 274, 296 (1971); Castle v. Hayes Freight Lines, 348 U.S. 61 (1954).

This summary of the principles of federal preemption fully supports the conclusion of the Court of Appeals that the federal purposes are impeded by the Hillsborough County ordinances and that the ordinances cannot survive the force of the Supremacy Clause. This conclusion applies despite the fact that the ordinances apply in the field of public health, an area often seen as peculiarly within the police power of the states. The Court has held that even "in a field which the states have traditionally occupied," their powers may be superseded by federal action if "that was the clear and manifest purpose of Congress." Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947). The "clear and manifest purpose of Congress" in enacting the regulations governing blood services, and of the executive Department of HEW in promulgating the National Blood Policy in implementation of the statutory scheme, was to assure a national, uniform, uninterrupted flow of safe blood and blood

Appendix

TITLE 42-THE PUBLIC HEALTH AND WELFARE

products. The County ordinances are manifestly inconsistent with that purpose. Therefore, the decision of the Court of Appeals holding them invalid should be affirmed.

Conclusion

The amicus curiae respectfully requests the Court to affirm the decision of the Court of Appeals for the Eleventh Circuit in favor of the Appellees.

Respectfully submitted,

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PART F-LICENSING OF BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES AND CONTROL OF RADIATION

SUBPART 1-BIOLOGICAL PRODUCTS

§262. Regulation of biological products

(a) Intrastate and interstate traffic; suspension or revocation of license as affecting prior sales

No person shall sell, barter, or exchange, or offer for sale, barter, or exchange in the District of Columbia, or send, carry, or bring for sale, barter, or exchange into any other State or possession into any foreign country, or from any foreign country into any State or Possession, any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood components or derivative, allergenic product, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man, unless (1) such virus, serum, toxin antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product has been propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license, issued by the Secretary as hereinafter authorized, to propagate or manufacture, and prepare such virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product for sale in the District of Columbia, or for sending, bringing, or carrying from place to place aforesaid;

and (2) each package of such virus, serum, toxin, antitoxin, vaccine, blood, blood component, or derivative, allergenic product, or other product is plainly marked with the proper name of the article contained therein, the name address, and license number of the manufacturer, and the date beyond which the contents cannot be expected beyond reasonable doubt to yield their specific results.

(c) Inspection of establishment for propagation and preparation

Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried or brought from any State or Possession into any other State or Possession or into any foreign country, or from any foreign country into any State or Possession.

(d) Regulations governing licenses

Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products described in subsection (a) of this section may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. All such licenses shall be

issued, suspended, and revoked as prescribed by regulations and all licenses issued for the maintenance of establishments for the propagation or manufacture and preparation, in any foreign country, of any such products for sale, barter, or exchange in any State or possession shall be issued upon condition that the licensees will permit the inspection of their establishments in accordance with subsection (c) of this section.